Michael F. Ram (SBN 104805)
mram@forthepeople.com
Marie N. Appel (SBN 187483)
mappel@forthepeople.com
MORGAN & MORGAN COMPLEX LITIGATION GROUP
711 Van Ness Avenue, Suite 500
San Francisco, CA 94102
Telephone: (415) 358-6913
Facsimile: (415) 358-6923

Glenn A. Danas (SBN 270317)
GDanas@RobinsKaplan.com
ROBINS KAPLAN LLP
2049 Century Park East, Suite 3400
Los Angeles, CA 90067
Telephone: (310) 229-5410

Kevin Hannon
(To be admitted *Pro Hac Vice*)
khannon@forthepeople.com
MORGAN & MORGAN COMPLEX LITIGATION GROUP
1641 Downing Street
Denver, CO 80218
Telephone: (303) 264-1769
Facsimile: (303) 264-1795

Justin Sobodash (SBN217450)
Justin@Sobodashlaw.com
LAW OFFICE OF JUSTIN SOBODASH, PC
8335 W. Sunset Blvd., Ste. 366
West Hollywood, CA 90069
Telephone: (323) 337-9010
Facsimile: (323) 656-7155

Attorneys for Plaintiffs and the Proposed Classes

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MICHAEL BASTASCH and DOUGLAS MEST, on behalf of himself and all others similarly situated,

Plaintiffs,

v.

KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC,

Defendants.

CASE NO.:

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs, Dr. Michael Bastasch and Dr. Douglas Mest ("Plaintiffs"), on behalf of themselves and all others similarly situated ("Class Members" or the "Class"), file this class action complaint against Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively "Philips" or "Defendants"). On personal knowledge of their own circumstances and upon investigation and information and belief of their counsel, Plaintiffs allege the following:

INTRODUCTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC manufacture and sell a variety of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and ventilators that treat respiratory failure. In general, each of these devices expresses air into patients' airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed. Without these devices, some patients may experience severe symptoms, including heart attack, stroke, and death by asphyxiation.

2. On April 26, 2021, Philips issued a public warning regarding potential health risks related to sound abatement foam used in specific Philips CPAP devices, BiPAP devices, and Mechanical Ventilators.

3. On June 14, 2021, Philips announced a recall of many of its CPAP/BiPAP machines and its ventilators (the "Recalled Breathing Machines").[1] Specifically, the Recalled Breathing Machines contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Philips announced that this foam may break down and be inhaled or ingested. Further, the PE-PUR foam may emit volatile organic compounds ("VOCs") that may be inhaled or ingested, adversely affect organs, and are

[1] These include the following models: E30; DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV, S/T, AVAPs; OmniLab Advanced Plus; SystemOne (Q Series); DreamStation CPAP, Auto CPAP, BiPAP; DreamStation Go CPAP, APAP; Dorma 400, 500 CPAP; REMStar SE Auto CPAP; Trilogy 100 and 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30; A-Series BiPAP V30 Auto; A-Series BiPAP A40; and A-Series BiPAP A30.

carcinogenic. Philips admitted that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."

4. Polyurethane is a polymer composed of organic units joined by carbamate (urethane) links. Polyurethanes are produced by reacting an isocyanate containing two or more isocyanate groups per molecule (R-(N=C=O)~) with a polyol containing on average two or more hydroxyl (O-H) groups per molecule in the presence of a catalyst or by activation with ultraviolet light.

5. Polyurethanes, especially those made using aromatic isocyanates, contain chromophores that interact with light. When polyurethane foam, which is made using aromatic isocyanates, is exposed to visible light, it discolors, turning off-white to yellow to reddish brown, and finally to black.

6. Isocyanates are known toxic substances, and include substances classified as potential human carcinogens. The health effects of isocyanate exposure include, among other things, irritation of skin and mucous membranes, chest tightness, and difficulty breathing. Isocyanates include compounds classified as potential human carcinogens and are known to cause cancer in animals. The additional known hazardous effects of isocyanate exposures are occupational asthma and other lung problems, as well as irritation of the eyes, nose, throat, and skin.

7. Degradation of polyurethane can result in the material becoming hard and friable, which can cause particles to be propelled by air movement. Degradation of the polyester polyurethane into volatile components (which may include hydrogen cyanide, and other toxic components) which are known toxic substances that can be ingested into the airways, absorbed on skin and tissue, or into the bloodstream. If depolymerization of the urethane occurs, degradation into isocyanate can result. Additionally, amines, glycols, and phosphate, also known toxic substances, may produce additional risks.

8. Philips' ventilators and CPAP/BiPAP machines are used in a high humidity, elevated-temperature (95-110°F) application complicated by the presence of bacteria and potential fungal growth. Polyester polyurethane is particularly sensitive to degradation from heat, oxygen (ozone), sunlight (ultraviolet) moisture, microbial and fungal attack. The properties of polyester polyurethanes have been well known and well documented in the scientific literature for many years well before Philips started

manufacturing the Recalled Breathing Machines.

9. The selection of polyester polyurethane by Philips for application in its ventilator and CPAP/BiPAP machines was highly inappropriate in that it breached the relevant standard of care because all of the health and safety risks set forth in the recall were known before the sale of any of the Recalled Breathing Machines and imminently foreseeable, while safe alternatives were readily available.

10. Furthermore, Philips knew or should have known about these very substantial and material health risks associated with the degradation of polyester polyurethane before any of these machines were sold and nonetheless used the material because it was expedient. In so doing, Defendants knowingly subordinated the health interests of their customers to their own financial gain.

11. Defendants now report in the recall that "based on testing there are possible risks to users related to this type of foam," and that "Philips has received reports of possible patient impact due to foam degradation."

12. Plaintiffs are informed and believe that these "risks" and certainty of degradation were known before any of the Recalled Breathing Machines were sold, because the properties of polyester polyurethane and likelihood of degradation in this application were known to the industry, were common knowledge to polymer experts and were readily available and known to Defendants before the machines went to market.

13. Defendants defrauded Plaintiffs and the Class at the time and place of each sale by failing to disclose the risk of harm — risks which were known or should have been known before the Recalled Breathing Machines were sold. Defendants' awareness of the properties of polyester polyurethane in this application, namely, high temperature, high moisture and susceptibility for fungi and microbes would lead to degradation and the inevitable and known health risks, required that Defendants disclose these risks before every sale of the products.

14. Consumers who use the Recalled Breathing Machines have complained about black particles in their machines for several years. Philips, however, did not warn the public or its customers about the hazards associated with the use of the Recalled Breathing Machines until late April 2021, and did not recall the Recalled Breathing Machines until June 14, 2021.

15. The recall of the Recalled Breathing Machines coincides with the launch of Defendants' next generation of products, which purportedly do not suffer from the same PE-PUR foam issues. Indeed, on April 13, 2021, Philips announced its next generation "DreamStation 2" device, just prior to its April 26, 2021 initial warning to the public regarding the danger posed by sound abatement foam in its prior generation of sleep apnea devices. The only option that Philips currently offers to its customers–many of whom need and rely on the Recalled Breathing Machines–is to purchase a newer model, thus further profiting from its own wrongdoing.

16. As Philips has explained in form letters sent to Class Members, it does not have a concrete timeline for replacing or repairing any of the Recalled Breathing Machines and warns that furnishing replacement devices "may take some time."

17. Plaintiffs and the members of the Class would not have purchased these products had the Defendants disclosed the health risks before each sale.

18. As a result of Plaintiffs' and Class Members' past, present and ongoing use of the Recalled Breathing Machines, Plaintiffs and Class Members have had in the past and will continue to have significant exposure to toxic chemicals present in the degradation of the PE-PUR foam used by Defendants, due to their inhalation and/or ingestion of the degradation products of the PE-PUR foam, which in turn entered their lungs and their bloodstream. Because of their past and present exposure to the degradation products of Defendants' PE-PUR foam, Plaintiffs and Class Members have already suffered in the past and continue to presently suffer an increased risk of serious illness, disease, and disease process caused by their exposure compared to the risk of the public at large of developing the same illnesses, diseases or disease processes, and compared to their chances of developing the illness, disease or disease process had they not been exposed to the degradation products of Defendants' PE-PUR foam, including an increased risk of headache, irritation, inflammation, respiratory injury, carcinogenic effects, and adverse effects to other organs such as the kidney and liver.

19. As a result of Defendants' actions, and the resulting exposure of Plaintiffs and Class Members to the toxic degradation products of Defendants' PE-PUR foam, and the present increased risk of illness, disease and disease process caused by their exposure to the degradation products of the PE-

PUR foam, Plaintiffs and Class Members have incurred the present economic loss of the current need to expend money to obtain medically necessary diagnostic testing for the early detection or illness, disease, or disease process as a result of the increased risk caused by their exposure to the toxic degradation products of the PE-PUR foam.

20. Such diagnostic testing is medically necessary to ensure that disease processes can be immediately identified and aggressively treated and is different from monitoring received by the general population.

21. The failure to disclose the known risks and presently existing health risks of the Recalled Breathing Machines also constituted an unfair business practice in that it was unfair and fraudulent to consumers and uniformly impacted and damaged Plaintiffs and all Class Members who would not have otherwise purchased the Recalled Breathing devices.

22. Defendants' warranty promising that the Recalled Breathing Machines would be "free from defects of workmanship and materials" was false, misleading and unlawful in that Defendants breached the warranties, express and implied.

23. Plaintiffs and Class Members have therefore suffered in the past and continue to suffer an invasion of their legally protected interest in not being exposed to toxic chemicals at levels sufficient to cause an increased risk of illness, disease or disease process, including cancer, and in the resulting present economic loss resulting from the need to incur medically necessary testing for the early detection of that illness, disease, or disease process associated with Defendants' toxic PE-PUR foam.

24. Plaintiffs individually, and on behalf of the Medical Monitoring Subclass Class Members, have suffered present injury and seek compensatory damages for their need for diagnostic testing arising out of past and ongoing exposure to chemical releases, discharges, and leaks of toxic chemicals due to foam degradation. These damages include the cost of a program of diagnostic testing for the early detection of illness, disease, or disease processes made necessary because of past and ongoing exposure to the releases of toxic carcinogenic gases caused by Defendants.

25. Plaintiffs individually, and on behalf of the Device Cost Subclass Members have suffered present injury and seek compensatory damages arising out of the loss of use of the Recalled Breathing

Machines in the form of reimbursement of the purchase cost of the Recalled Breathing Machines, and the difference in cost between the Recalled Breathing Machines and their replacement breathing machines.

JURISDICTION

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. section 1332(d)(2) because this is a class action in which the matter in controversy exceeds $5,000,000.00 exclusive of interest and costs, and Plaintiffs are citizens of states that are different than the states of which Defendants are citizens.

27. Venue is proper in this Court pursuant to 28 U.S.C. section 1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' and the Class Members' claims occurred in this District, and Defendants are subject to the Court's personal jurisdiction.

28. As a result of Defendants' advertising, selling, and distributing the Recalled Breathing Machines to purchasers throughout California, either directly or indirectly through third parties or related entities, Defendants obtained the benefits of California law and profited from California commerce.

29. Defendants conducted systematic and continuous business activities in and throughout the state of California and otherwise intentionally availed themselves of the markets of the state of California through the promotion and marketing of their products.

PARTIES

30. Plaintiff Dr. Michael Bastasch is a radiation oncologist and currently a resident of Dallas, Texas. From 2006 through March 2019, Dr. Bastasch resided in San Francisco, California full-time.

31. Plaintiff Dr. Douglas Mest, an anesthesiologist, is a resident of Signal Hill, California.

32. Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.

33. Defendant Philips North America LLC is a Delaware company with its principal place of business in Cambridge, Massachusetts.

34. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.

35. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

FACTUAL ALLEGATIONS

A. PLAINTIFFS' FACTUAL ALLEGATIONS.

36. In 2015, Dr. Bastasch was diagnosed with sleep apnea by his physician in San Francisco.

37. On or about August 18, 2015 Plaintiff Bastasch ordered for delivery to his San Francisco residence a PR System One REMStar 60 Series Auto with Bluetooth CPAP machine and PR System One 60 Series Heated Tube Humidifier with Heated Tube (together, "REMStar CPAP Device"). Dr. Bastasch paid $623.00 for his REMStar CPAP Device.

38. In late August 2015, Dr. Bastasch began regularly using his REMStar CPAP Device while sleeping. Dr. Bastasch used his Philips REMStar CPAP Device any time he slept, including during naps and his usual nighttime sleep.

39. Dr. Bastasch learned of the Philips Recall in July, 2021 and immediately discontinued use of his Philips REMStar CPAP Device.

40. As a direct and proximate result of the use of his Recalled Breathing Machine, Dr. Bastasch has inhaled and/or ingested degradation products of Defendants' toxic PE-PUR foam which has entered his lungs and bloodstream, and resulted in an increased risk of illness, disease or disease process caused by his exposure.

41. Dr. Bastasch would not have purchased this product if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials.

42. Because of the recall, Dr. Bastasch has been forced to cease using his Philips REMStar CPAP Device. Dr. Bastasch has since purchased a new CPAP device, paid for entirely out-of-pocket, at a cost of $1,100.00.

43. Dr. Bastasch contacted Philips directly after he learned of the recall and was told that Philips would not be offering refunds or credits at this time.

44. In approximately September 2016 Dr. Mest was diagnosed with sleep apnea.

45. On October 19, 2016, Dr. Mest ordered a Respironics Model DSX500HIIC CPAP device, at a cost of $1,596.00, of which Dr. Mest paid a portion and his insurance company paid a portion.

46. In late October 2016 Dr. Mest commenced regular use of his Respironics CPAP device while sleeping.

47. Dr. Mest learned of the Philips Recall in July 2021 and immediately discontinued use of his Philips Respironics CPAP device.

48. As a direct and proximate result of the use of his Recalled Breathing Machine, Dr. Mest has inhaled and/or ingested degradation products of Defendants' toxic PE-PUR foam which has entered his lungs and bloodstream, and resulted in an increased risk of illness, disease or disease process caused by his exposure.

49. Dr. Mest would not have purchased this product if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials.

50. Because of the recall, Dr. Mest was forced to stop using his Respironics CPAP device and has been forced to find a replacement. The replacement, which Dr. Mest found online, was $1,200.00. Dr. Mest paid this replacement cost out of pocket.

B. CPAP MACHINES, BIPAP MACHINES, AND VENTILATORS TREAT SERIOUS CONDITIONS.

51. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. This may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments.

52. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.

53. Other therapies to treat sleep apnea include BiPAP therapy and Automatic Positive

Airway Pressure ("APAP"). BiPAP machines provide two different pressure settings, one for inhalation and one for exhalation.

54. Patients who use CPAP or BiPAP machines typically use them every day when they sleep. Symptoms may return quickly if therapy is discontinued.

55. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into the blood. Many underlying conditions can cause respiratory failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug abuse. Respiratory failure can be fatal.

56. Mechanical ventilators, usually called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. The COVID-19 crisis has led to a significant increase in the demand for ventilators in the United States and worldwide.

C. PHILIPS RECALLED ITS PRODUCTS DUE TO THE PRESENTLY EXISTING SERIOUS HEALTH HAZARDS FROM THE FOAM THAT IT UTILIZED.

57. Philips manufactures and sells CPAP machines, BiPAP machines, and ventilators, among other products. According to Philips's 2020 Annual Report, Sleep & Respiratory Care constituted approximately 49% of Philips's total sales in its Connected Care line of business, which in turn accounted for 28% of Philips's overall sales of about €19.535 billion.

58. Philips's flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary Respironics, which Philips acquired in 2008.

59. Many of Philips's CPAP and BiPAP machines and ventilators contain PE-PUR foam for sound abatement. Owing to the design of the machines, air passes through this foam before it is pumped into the patient's airway.

60. On April 13, 2021, Philips announced that it was launching the DreamStation 2, the next-generation machine in its DreamStation product family.

61. Less than two weeks later, on April 26, 2021, Philips announced the recall and, in the same release, shockingly started pushing consumers to purchase its latest generation device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

62. In fact, Defendant Koninklijke Philips N.V. announced its First-Quarter Results for 2021 on April 26, 2021, the same date that Defendants first issued the safety notice on its Recalled Breathing Machines. According to CEO Frans van Houten, "Philips is the market leader in sleep apnea" and "sleep app devices."[2] Excluding the impact of a EUR 250 million provision related to the Recalled Breathing machines, income from continuing operations improved by EUR 139 million year-on-year.[3] Van Houten represented that the recall of the Recalled Breathing Machines came out of "post-market surveyance" where user reports "lead us to do this warning," downplaying and omitting any previous knowledge of the carcinogenic properties that are present in degradation of polyester-based polyurethane foam.[4] While Philips sales were impacted due to the Recalled Breathing Machines, it was on a "limited basis" because the United States is Defendants' biggest market and the majority of demand is to receive the new DreamStation 2.[5]

---

[2] https://www.fool.com/earnings/call-transcripts/2021/04/26/koninklijke-philips-nv-phg-q1-2021-earnings-call-t/ (last accessed August 10, 2021).
[3] https://www.philips.com/a-w/about/news/archive/standard/news/articles/2021/20210728-q2-2021-results-philips-ceo-frans-van-houten-on-bloomberg-tv.html (last accessed August 10, 2021).
[4] https://www.fool.com/earnings/call-transcripts/2021/04/26/koninklijke-philips-nv-phg-q1-2021-earnings-call-t/ (last accessed August 10, 2021).
[5] *Id.*

63. On June 14, 2021, Philips then issued a further statement:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE- PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.

64. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family." Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification* advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.*
>
> For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.*
>
> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as

> required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.

65. On the same day, Philips provided additional information in an announcement entitled "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care."

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

66. Philips' announcement detailed two types of hazards from the PE-PUR foam in the devices. First, the announcement described dangers due to foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine
>
> - Toluene Diisocyanate

- Diethylene glycol

67. The European Union considers Toluene Diisocyanate "highly toxic" and has concluded that Toluene Diamine "cannot be considered safe for use" even as a hair dye.

68. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

69. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long- term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> - Dimethyl Diazine
>
> - Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)

Dimethyl Diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) are both known toxic substances.

70. Philips admitted that the risks of these VOCs include that they "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

71. Although Philips did not disclose these health risks until June 2021, Philips has known about these health risks for a long time. For example, customers have complained to Philips about black particles in their machines for several years as evidenced by forum posts and statements from those that

follow the industry.

72. A sampling of these online complaints are as follows [sic throughout]:

a. Doug, 2017[6]

The water reservior will only last one night and if it gets very close to empty a burnt plastic smell fills the airway and you will wake up with a terrible toxix smell. In my experience this happens on heat settings i, 2, or 3.

b. Lamaan Whyte, July, 2021[7]

My wife and I have been using Dreamstaions for just over a year. Soon afterwards, we both began developing nasal and respiratory problems. Just recently, my wife's machine begun showing lots of foam specks in the dehumidifier; at about the same time, she started developing mysterious skin rashes. Philip's announcement that their machines were potential nightmares provides a highly plausible explanation for these medical problems. We immediately stopped using the Dreamstations (dragging 10-year-old machines out of mothballs); whether this will fix our medical issues remains to be seen, but we both are sleeping easier.

c. A Deschene, August, 2021[8]

Holy cow! I just stumbled onto this while looking for supplies. I have been waking up because something has been sucked down into my lungs and I couldn't figure out what it was. It's awful when it happens. I can't get a breath in or out then I cough and cough until my throat and lungs hurt. I clean mine daily and inspect to be sure there is nothing in the water yet it kept happening. Just WOW!!!!

\\\

\\\

d. Doris Queener, August, 2021[9]

Philips reports very low number of complaints, but I've had issues for several months--sinus headaches, cough, dry mouth and throat. I couldn't get an appointment with a sleep doctor until August 2nd. An appointment with a regular doctor didn't even bring up the use of a CPAP. I was not

[6] https://www.google.com/search?q=philips+dreamstation+reviews (last accessed August 10, 2021).

[7] *Id.*

[8] https://www.youtube.com/watch?v=f9jmaT_GMkc (last accessed August 12, 2021).

[9] https://www.youtube.com/watch?v=j6wsvyxup-Q (last accessed August 12, 2021).

> notified of the recall and discovered the problem through internet research on problems with my new F&P mask as compared to the old one (with foam insert.) I have found several YouTube sites that have helped so much. Living in a rural area with Medicare coverage limits options.

D. PHILIPS HAS NOT REPLACED ANY DEVICES AND HAS NO PLAN TO DO SO.

73. Philips's recall does not actually provide patients with new CPAP, BiPAP, or ventilator devices, but suggests consumers can buy the next generation of its product. As Philips's June 14, 2021 announcement makes clear:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.

74. Thus, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacement foam.

75. At the same time, Philips intends to profit from the so-called recall by selling more of its next generation product, the DreamStation 2. Philips intentionally timed the recall to coincide with the launch of the DreamStation 2.

76. Due to the design of the Recalled Breathing Machines, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. There is also a general shortage of available replacement machines.

77. But patients need to use their machines every day, or else their symptoms—which can be

severe and life-altering—may return.

78. As a result, the recall by Philips leaves patients without safe, free options. Patients may buy Philips's next-generation product or a competitor's product—at full price.

79. Pursuant to the statements issued by Philips that are set forth above, Philips has admitted that the Recalled Breathing Machines are defective and unsafe. The Recalled Breathing Machines are effectively worthless and/or have a far lesser value than what customers paid and would not have been purchased by patients if they were informed of the defect at the time of sale.

80. Plaintiffs and the Class members have all suffered economic injuries as a result of their purchase of the Recalled Breathing Machines.

81. As a result of Defendants' misconduct, Plaintiffs and Class Members have suffered actual damages by their purchase of the Recalled Breathing Machines.

82. The damages suffered by Plaintiffs and Class Members were not foreseeable from the perspective of Plaintiffs and the Class, and Defendants did not warn Plaintiffs and the Class that the Recalled Breathing Machines are defective and unsafe.

83. Defendants have failed adequately to compensate Plaintiffs and the Class for damages suffered as a result of the Recalled Breathing Machines.

84. It is unlikely that most Class Members could afford to seek recovery against Defendants on their own. A class action is therefore the only viable, economical, and rational means for Class Members to recover from Defendants for the damages Defendants have caused.

E. PLAINTIFFS AND CLASS MEMBERS HAVE ALREADY BEEN INJURED BY PAST SIGNIFICANT EXPOSURE TO DEFENDANTS' PE-PUR FOAM AND RESULTING PAST, PRESENT AND ONGOING INCREASED RISK OF DISEASE, REQUIRING THE EXPENDITURE OF THE COST OF MEDICALLY NECESSARY DIAGNOSTIC TESTING.

85. Plaintiffs and Class Members have used the Recalled Breathing Machines during the time Defendants have admitted to the release of toxic chemicals found in the degraded polyester polyurethane foam.

86. As a result of Defendants' tortious design of the Recalled Breathing Machines, Plaintiffs

and Class Members have in the past and continue to be significantly exposed to Defendants' hazardous chemicals by inhaling and/or ingesting them and absorbing them through their respiratory tract, where they are absorbed by skin and tissue, and enter into their bloodstreams.

87. Chemicals such as isocyanate, toluene diisocyanate, dimethyl diazine, phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) and other volatile organic compounds found in the PE-PUR foam, or degradation of the foam, are proven hazardous substances, including but not limited to being carcinogenic.

88. As a proximate result of Defendants' tortious conduct, Plaintiffs and Class Members have in the past been and are presently at an increased risk of illness, disease, or disease process, including cancer, requiring them to incur, both presently and in the future, the cost of medically necessary diagnostic testing for the early detection of illness, disease process or disease related to hazardous properties of the toxins emitted from the Recalled Breathing Machines.

89. Plaintiffs and Class Members have presently suffered injury proximately caused by Defendants' tortious conduct. Plaintiffs have a legally protected interest in not being exposed to toxic chemicals, such as Defendants' toxic PE-PUR foam, and at levels that can result in an increased risk of illness, disease, or disease process. Plaintiffs and Class Members also have a legally protected interest in avoiding the present and future medical need for expensive diagnostic testing. The past and ongoing exposure to Defendants' toxic PE-PUR foam and resulting past and ongoing increased risk of illness, disease or disease process associated with PE-PUR foam and its degradation, has caused the present and future need to incur the cost of medically necessary diagnostic testing for the early detection of disease as a result of Defendants' advertisement and sale and Plaintiffs and Class Members' use of the Recalled Breathing Machines constituting an invasion of the legally protected interests of Plaintiff and Class Members and injury to Plaintiffs and Class Members. Plaintiff and Class Members would not have the present and future need to incur the cost of the diagnostic testing to determine the presence of illness, disease, or disease process related to exposure of PE-PUR foam but for the past and ongoing exposure they have suffered through the tortious conduct of Defendants.

90. Monitoring procedures exist that make possible the early detection of the toxic and

carcinogenic effects of the degradation products of the PE-PUR foam used in Defendants' Recalled Breathing Machines. These monitoring procedures are different than for the unexposed populations, because the general unexposed population does not receive this testing as a routine matter of course, including because they are designed to detect diseases known to be associated with exposure to polyester-based polyurethane foam. The monitoring procedures will benefit Plaintiffs and Class Members since they will allow for the early detection of latent disease associated with exposure to toxic PE-PUR foam. Catching cancer early often allows for more treatment options. Overall outlook depends on early diagnosis; the sooner a person is checked, the better the outcome will be.[10]

91. Medical monitoring is recognized as beneficial for early detection where there is an increased risk of disease from exposure to hazardous substances.[11] The purpose of a medical monitoring program is early identification of latent or unrecognized illness, disease or disease process so that early treatment can be given to reduce the impacts of the toxic exposure.[12] Medical monitoring is widely accepted as a necessary and appropriate response to toxic exposure.[13]

92. Plaintiffs and Class Members have the present need of diagnostic testing to diagnose properly the warning signs of the illness, disease, and/or disease process resulting from exposure to the toxins released by Defendants' PE-PUR foam. Finding illness, disease and disease processes early allows for more treatment options. If left to when the disease becomes obvious, Plaintiffs and Class Members will lose valuable treatment time. These monitoring procedures are different from what would normally be recommended in the absence of exposure to the degradation products of Defendants' PE-

---

[10] https://www.cancer.org/content/dam/CRC/PDF/Public/8671.00.pdf (last accessed August 10, 2021).
[11] ATSDR's Final Criteria for Determining the Appropriateness of a Medical Monitoring Program Under CERCLA, 60 FR 38841, July 28 1995.
[12] *Id.*
[13] *See* http://www.c-8medicalmonitoringprogram.com/docs/med_panel_education_doc.pdf (last accessed August 10, 2021); Department of Environmental Health, *Fernald Medical Monitoring Program*, UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE, https://med.uc.edu/eh/research/projects/fcc/fmmp-history (last accessed August 10, 2021); Environmental Health & Safety, *Pesticide Users Medical Monitoring Program*, UNIVERSITY OF FLORIDA (revised Jan. 21, 2014), http://www.ehs.ufl.edu/programs/ih/pesticide/ (last accessed August 10, 2021); World Trade Center Health Program, *About the Program*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/wtc/about.html (last updated Dec. 15, 2017).

PUR foam. Plaintiffs and Class Members present need to incur the cost of diagnostic testing is reasonably medically necessary as a direct and proximate result of Defendants' conduct due to the Plaintiffs' and Class Members' past and ongoing exposure to the degradation products of Defendants' PE-PUR foam.

93. Plaintiffs and the Class are currently in need of costly diagnostic testing. Specifically, they need monitoring procedures that are reasonably necessary to enable Plaintiffs and Class Members to obtain early detection and diagnosis of illness, disease and disease process, including abnormalities indicative of cancer, made medically necessary as the proximate result of Defendants' tortious conduct described herein.

94. Plaintiffs and Class Members seek as damages the costs of such diagnostic testing for the early detection of illness, disease, and disease process, and to allow for early treatment beneficial to Plaintiffs and Class Members, or in the alternative, the award of the reasonable and necessary costs for the establishment of a court-supervised program of diagnostic testing through injunctive relief.

95. Plaintiffs and Class Members also seek all other available and necessary relief in connection with this claim.

PLAINTIFFS' CLAIMS ARE NOT BARRED BY THE STATUTE OF LIMITATIONS

96. Defendants knew the Recalled Breathing Machines were defective prior to the time of sale and intentionally and wrongfully concealed material information concerning its products from Plaintiffs, members of the Class and their physicians, and the general public, all the while continually marketing and promoting the Recalled Breathing Machines. Defendants' acts of fraudulent concealment include failing to disclose critical safety information about the true risks associated with the Recalled Breathing Machines.

97. Because the Recalled Breathing Machines defects are latent and not detectable until manifestation, Plaintiffs and members of the Class were not reasonably able to discover the Recalled Breathing Machines were defective and unreliable until the recent recall, despite their exercise of due diligence.

98. Therefore, the applicable statutes of limitation have been tolled with respect to any claims that Plaintiffs or the Class Members have brought or could have brought as a result of the unlawful or fraudulent course of conduct described herein.

99. As a result, Defendants are estopped from pleading any statute of limitations defense. Defendants actively concealed and misrepresented to Plaintiffs and the Class Members essential facts that underlay Plaintiffs' and the Class Members' claims. Therefore, Defendants prevented Plaintiffs and the Class Members from learning about these claims earlier. Had Plaintiffs and the Classes been aware of the facts which Defendants misrepresented and concealed, they could have acted to prevent damage to themselves.

CLASS ACTION ALLEGATIONS

100. Plaintiffs brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and the classes. This action satisfies requirements set forth in Rule 23(a) and Rule 23(b)(3).

101. Plaintiffs advances this action on behalf of the following classes (the "Classes"):

> Nationwide Class: All persons in the United States who have purchased a Recalled Breathing Machine for personal use. Excluded from the Nationwide Class are Defendants, their legal representatives, assigns and successors and any entity in which Defendants have a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.
>
> Subclass A, Medical Monitoring Subclass: All members of the Nationwide Class that have used a Recalled Breathing Machine for at least a month.
>
> Subclass B, Recalled Breathing Machine Cost Subclass: All members of the Nationwide Class that have purchased a Recalled Breathing Machine, including those who have incurred an insurance deductible or copay for the purchase of a Recalled Breathing Machine.
>
> California Class: All individuals and entities in the State of California who purchased a Recalled Breathing Machine for personal use. Excluded from the California Class are Defendants, their legal representatives, assigns and successors and any entity in which Defendants have a controlling interest. Also excluded is the judge to whom this case is

assigned and any member of the judge's immediate family and judicial staff.

Subclass A, Medical Monitoring Subclass: All members of the California Class that have used a Recalled Breathing Machine for at least one month.

Subclass B, Recalled Breathing Machine Cost Subclass: All members of the California Class that have purchased a Recalled Breathing Machine, including those who have incurred an insurance deductible or copay for the purchase of a Recalled Breathing Machine.

Claims for personal injury are specifically excluded from the Classes.

102. Numerosity (Rule 23(a)(1)). Although the actual size of the Classes is unknown, Plaintiffs are informed and believe that the proposed Nationwide Class is comprised of at least millions of individuals, and that millions of customers nationwide have purchased the Recalled Breathing Machines, making joinder impractical. The proposed California Class contains at least thousands of individuals who purchased a Recalled Breathing Machine. The disposition of the claims of these Class Members in a single class action will provide substantial benefits to all parties and to the Court.

103. Commonality (Rule 23(a)(2)). There exist questions of law and fact common to all Class Members. Common questions include, but are not limited to, the following:

a. Whether Defendants were negligent in manufacturing and selling the Recalled Breathing Machines;

b. Whether Defendants failed to warn consumers regarding the risks of the Recalled Breathing Machines;

c. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

d. Whether Defendants are strictly liable for the manufacture and sale of the Recalled Breathing Machines;

e. Whether Defendants breached the express warranties to Plaintiffs and the Class;

f. Whether Defendants breached their implied warranties to Plaintiffs and the Class;

g. Whether the chemicals in or emitted from the polyester-based polyurethane foam is a proven

hazardous substance;

h. Whether Plaintiffs and Class Members have been significantly exposed to Defendants' polyester-based polyurethane foam;

i. Whether Plaintiffs and Class Members are at an increased risk of illness, disease, or disease process because of their exposure to Defendants' toxic polyester-based polyurethane foam;

j. Whether early detection of illness, disease or disease process will provide benefits to Plaintiffs and members of the Class;

k. The appropriate nature of class-wide equitable relief;

l. Whether Defendants were unjustly enriched by the sale of the Recalled Breathing Machines; and

m. Whether Defendants should be ordered to disgorge, for the benefit of Class Members, all or part of their ill-gotten profits received from the sale of defective Recalled Breathing Machines and/or to make full restitution to Plaintiff and Class Members.

104. Typicality (Rule 23(a)(3)). The claims of the representative Plaintiffs are typical of the claims of Class Members, in that the representative Plaintiffs, like all Class Members, purchased defective Recalled Breathing Machines. The representative Plaintiffs, like all Class Members, has suffered a common injury: they paid for a defective product that they would not have purchased had they known the truth about it. The factual basis of Defendants' misconduct is common to all Class Members.

105. Adequacy (Rule 23(a)(4)). Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel with substantial experience in prosecuting consumer class actions, including actions involving defective consumer products, failure to disclose material information regarding product safety and violation of consumer protection statutes. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Classes and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interests adverse to those of the Classes.

106. Predominance of Common Questions (Rule 23(b)(3)). Common questions of law and

fact predominate over any questions involving individualized analysis. Fundamentally, there are no material questions of fact or law that are not common to Class Members. The performance of the Recalled Breathing Machines relative to their represented qualities is a common question, as is the Defendants' knowledge regarding the Recalled Breathing Machines performance and Defendants' uniform omission to Class Members of these material facts. Common questions of law include whether Defendants' conduct violates consumer protection statutes and other laws, and the Class Members' entitlement to damages and remedies.

107. Superiority (Rule 23(b)(3)). Plaintiffs and Class Members have suffered and will continue to suffer harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the subject controversy. Most Class Members likely would find the cost of litigating their individual claims to be prohibitive and will have no effective remedy at law. Thus, absent a class action, Class Members will continue to incur damages and Defendants' misconduct will proceed without remedy. Class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication. There is no impediment to the management of this action because of the virtual identity of the questions of law and fact common to all Class Members.

108. Injunctive Relief (Rule 23(b)(2)). Defendants, through their uniform conduct, acted or refused to act on grounds generally applicable to the Class as a whole, making injunctive relief appropriate to the Class as a whole.

109. Plaintiffs seek class-wide injunctive relief on grounds consistent with the standards articulated in Rule 23(b)(2) that establish final injunctive relief as an appropriate class-wide remedy, in that Defendants continues to provide half-truths and misleading information about the Recalled Breathing Machines and continues to omit material facts regarding the Recalled Breathing Machines. The injuries suffered by Plaintiffs and the Classes as a result of Defendants' actions are ongoing.

FIRST CAUSE OF ACTION
Design Defect Strict Liability

110. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

111. The design of the Recalled Breathing Machines, including, but not limited to, design and use of the PE-PUR foam and the placement of the foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

112. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

113. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestion.

114. Safer, alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe PE-PUR foam.

115. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

116. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.

117. As a direct and proximate result of Defendants' unreasonably dangerous activities, and the resulting exposure therefrom, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above, including the costs of diagnostic testing for the early detection of illness, disease, and disease process and the purchase and replacement costs of Recalled Breathing Machines in an amount to be determined at trial.

SECOND CAUSE OF ACTION
Negligent Design

118. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109

of this Complaint.

119. Defendants negligently designed the Recalled Breathing Machines. Philips owed Plaintiff and the Class a duty to design the Recalled Breathing Machines in a reasonable manner. The design of the Recalled Breathing Machines, including but not limited to the design of the PE-PUR foam and the placement of the PE-PUR foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

120. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

121. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestion.

122. Safer, alternative machines from other manufacturers were available that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe foam.

123. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

124. The Recalled Breathing Machines did not perform in a safe and reliable manner as an ordinary consumer would expect.

125. As a direct and proximate result of Defendants' negligence, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above, including the costs of diagnostic testing for the early detection of illness, disease, and disease process and the purchase and replacement costs of Recalled Breathing Machines in an amount to be determined at trial.

\\\

\\\

\\\

THIRD CAUSE OF ACTION

Breach of Express Warranty

126. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

127. Defendants warranted that the Recalled Breathing Machines "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale." This Warranty formed the basis of the bargain that was reached with Plaintiffs and other members of the Class purchased the Recalled Breathing Machines.

128. Defendants were well aware of the defects in materials within two years of purchase of the Recalled Breathing Machines by Plaintiffs and all Class Members, but failed to disclose the defects. Therefore, Defendants are barred and estopped from asserting that warranty claims are barred based upon the two year warranty period. Plaintiffs and all Class Members were unaware of the defects in materials and could not have reasonably learned or discovered of such defects within two years of purchase.

129. Defendants breached this express warranty in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

130. Defendant breached the express warranty through the acts and omissions described above.

131. Had Plaintiffs and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

132. Plaintiffs and the members of the Class have had sufficient direct dealing with either Defendants or its agents (i.e., distributors and technical support) to establish privity of contract between Defendants, on one hand, and Plaintiffs and each of the other members of the Class on the other hand. Nonetheless, privity is not required here because Plaintiffs and each of the other members of the Class are the intended third-party beneficiaries of contracts between Defendants and its distributors, and specifically, of Defendants' express warranties. The distributors were not intended to be the ultimate

consumers of the Recalled Breathing Machines as the warranty agreements were designed for and intended to benefit the consumers.

133. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

134. Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above, including the costs of diagnostic testing for the early detection of illness, disease, and disease process and the purchase and replacement costs of Recalled Breathing Machines in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
Breach of Implied Warranty

135. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

136. Defendants designed, developed, and sold the Recalled Breathing Machines knowing that Plaintiffs and Class Members would use them.

137. Defendants are merchants of the Recalled Breathing Machines and marketed, promoted, and sold it to the consuming public.

138. Defendants expected the consuming public, including Plaintiffs and Class Members, to use the Recalled Breathing Machines as assisted breathing devices and such use was reasonably foreseeable. The Recalled Breathing Machines were not merchantable at the time that Defendants sold them.

139. By operation of law, Defendants, as manufacturers of the Recalled Breathing Machines and as the providers of a limited warranty for the Recalled Breathing Machines, impliedly warranted to Plaintiffs and the Class that the Recalled Breathing Machines were of merchantable quality that would pass without objection in the trade and safe for their ordinary and intended use.

140. Plaintiffs and members of the Class relied on that implied warranty.

141. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines, while appearing normal, contained defects as set forth herein rendering them unsuitable and unsafe for personal use by humans.

142. Had Plaintiffs and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

143. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

144. Defendants breached their implied warranties of merchantability because the Recalled Breathing Machines were not of merchantable quality and was defectively designed and was unfit for the ordinary purposes for which it was designed and used.

145. Defendants did not properly disclaim the warranty of merchantability and fitness for a particular purpose.

146. Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above, including the costs of diagnostic testing for the early detection of illness, disease, and disease process and the purchase and replacement costs of Recalled Breathing Machines in an amount to be determined at trial.

\\\

\\\

\\\

FIFTH CAUSE OF ACTION
Breach of the Magnuson-Moss Warranty Act

147. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

148. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully above.

149. Plaintiffs and members of the Class are consumers as defined in 15 U.S.C. section

2301(3).

150. Defendants are suppliers and warrantors as defined in 15 U.S.C. sections 230l (4)-(5).

151. The Recalled Breathing Machines are consumer products as defined in 15 U.S.C. section 2301(1).

152. Title 15 U.S.C. section 2310(d)(1) provides a cause of action for any consumer who is damaged by the failure of a warrantor to comply with the written and implied warranties.

153. Defendants warranty that the Recalled Breathing Machines "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale" is a "written warranty" within the meaning of 15 U.S.C. Section 2301(6).

154. Under 15 U.S.C. section 2301(7), Defendants extended the implied warranties to Plaintiffs and the Class. Defendants breached the implied warranties by selling Recalled Breathing Machines that were neither merchantable nor fit for their intended purpose.

155. Plaintiffs and the Class Members notified Defendants of the breach within a reasonable time and/or were not required to do so. Defendant was also on notice of the Recalled Breathing Machines from, among other sources, the complaints it received from Class Members.

156. Plaintiff need not provide further notice to Defendants of the breach of the written and implied warranties because Defendants have recalled the Recalled Breathing Machines and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy the breach of its obligations to the Class under the written and implied warranties or to cure the defect.

157. Plaintiffs and the members of the Class have had sufficient direct dealing with either Defendants or its agents (i.e., distributors and technical support) to establish privity of contract between Defendants, on one hand, and Plaintiffs and each of the other members of the Class on the other hand. Nonetheless, privity is not required here because Plaintiffs and each of the other members of the Class are the intended third-party beneficiaries of contracts between Defendants and its distributors, and specifically, of Defendants' written and implied warranties. The distributors were not intended to be the ultimate consumers of the Recalled Breathing Machines as the warranty agreements were designed for

and intended to benefit the consumer.

158. Pursuant to 15 U.S.C. section 2310(d)(3), the amount in controversy of Plaintiffs' individual claims meets or exceeds the sum of $25 and the amount in controversy of this action exceeds the sum of $50,000, exclusive of interest and costs. Plaintiffs, individually and on behalf of other Class Members, seek all damages permitted by law, including diminution in value of their Recalled Breathing Machines, in an amount to be proven at trial.

159. In addition, pursuant to 15 U.S.C. section 2310(d)(2), Plaintiffs and the Class Members are entitled to recover a sum equal to the aggregate amount of costs and expenses (including attorneys' fees based on actual time expended) determined by the Court to have reasonably been incurred by Plaintiffs and the Class Members in connection with the commencement and prosecution of this action.

\\\

\\\

FIFTH CAUSE OF ACTION
Breach of the Song-Beverly Consumer Warranty Act

160. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

161. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully above.

162. Under the Song-Beverly Consumer Warranty Act, Civ. Code section 1792 *et seq.*, every sale of consumer goods in the State of California is accompanied by both a manufacturer's and retail seller's implied warranty that the goods are merchantable.

163. The Recalled Breathing Machines are consumer goods within the meaning of the statute.

164. Defendants are each a "manufacturer" within the meaning of the statute.

165. Plaintiffs and members of the Class purchased Recalled Breathing machines in the State of California.

166. By operation of law, all Defendants made the express and implied warranties to Plaintiffs and the Class concerning the Recalled Breathing Machines.

167. Defendants have breached the implied warranties by selling recalled Breathing Machines

which were not of merchantable quality and which failed to perform the tasks for which they were intended and expose Plaintiffs and Class Members to serious risk of harm.

168. Civil Code section 1792, which provides that "[u]nless disclaimed in the manner prescribed by this chapter, every sale of consumer goods that are sold at retail in this state shall be accompanied by the manufacturer's and the retail seller's implied warranty that the goods are merchantable," has no privity requirement. Therefore, Plaintiffs and all other Class Members do not have to be in privity with any Defendant in order to enforce the implied warranties.

169. Plaintiffs and the Class Members are intended beneficiaries of the express and implied warranties between Defendants and its distributors and are therefore entitled to enforce the express and implied warranties against Defendants.

170. Defendants are fully aware of their breach of the express and implied warranties in that Defendants recalled the machines and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy the breach of its obligations to the Class under the warranties.

171. Further notice to Defendants of their breach of the warranties would be futile because Defendants are aware of and have acknowledged the defects in the Recalled Breathing Machines in the recall and, Defendants cannot provide to Plaintiffs and the Class any remedy other than replacement of the Recalled Breathing Machines or the cost of purchasing a non-defective comparable machine.

172. As a direct and proximate result of Defendants' breaches of the express and implied warranties, Plaintiffs and Class members have been damaged and seek relief including, but not limited to injunctive relief, restitution, compensatory damages, civil penalties, and attorneys' fees and costs.

SIXTH CAUSE OF ACTION
Violation of California Consumers Legal Remedies Act ("CLRA")

173. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

174. Defendants are "person[s]" as defined by California Civil Code section 1761(c).

175. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of California Civil Code sections 1770(a)(5), (a)(7), (a)(9), and (a)(14) when Defendants failed

to disclose the health risks of the PE-PUR foam in the Recalled Breathing Machines. Defendants violated the CLRA when they falsely represented the Recalled Breathing Machines were of a particular standard or quality. Defendants represented that the Recalled Breathing Machines were safe for users and suitable to be prescribed by physicians for patients who suffer from sleep apnea and respiratory failure. Plaintiffs and Class Members relied on Defendants' representations. Defendants further violated the CLRA when their so-called "recall" represented a remedy to the Recalled Breathing Machines that they do not have, and by understating and failing to disclose health risks resulting from the failure of the Recalled Breathing.

176. Defendants' deceptive practices were specifically designed to induce Plaintiff and Class Members to purchase the Recalled Breathing Machines. Class Members, their physicians, and/or third parties were persuaded to purchase the Recalled Breathing Machines developed and marketed by Defendants.

177. To this day, Defendants continue to engage in unlawful practices in violation of the CLRA. Defendants continue to falsely represent a presently-available remedy through their recall to Plaintiffs and Class Members but have failed to provide any kind of appropriate remedial options.

178. Plaintiffs served Defendants with notice of its CLRA violations by serving notice on August 13, 2021. A copy of the notices are attached to this Complaint as Exhibit A.

179. As a direct and proximate result of Defendants' conduct, and the resulting exposure therefrom, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above. Plaintiffs on behalf of themselves and for all others similarly situated, demand injunctive relief ordering Defendants to set up a refund program to replace and repair all Recalled Breathing Machines for Class Members, plus costs and attorneys' fees pursuant to California Civil Code section 1780(d). Plaintiffs will amend this complaint to request damages under this cause of action unless Defendants remedy the defect pursuant to Plaintiffs' demand letter.

SEVENTH CAUSE OF ACTION
Violation of California Unfair Competition Law- Unlawful Business Practice

180. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109

of this Complaint.

181. California Business and Professions Code section 17200 *et seq*. prohibits acts of unfair competition, which includes unlawful business practices.

182. Defendants engaged in unlawful business practices in failing to disclose the Recalled Breathing Machines contained hazardous materials.

183. Defendants' deceptive practices constitute an unlawful business practice in that the practices were specifically designed to induce Plaintiffs, Class Members, and their physicians or third parties upon whom Plaintiffs and Class Members relied to provide appropriate guidance regarding reliable breathing assistance, to purchase on Class Members' behalf the Recalled Breathing Machines and use it.

184. To this day, Defendants have engaged and continue to engage in unlawful business practices by failing to provide safe replacement machines and by understating and failing to disclose health risks resulting from the failure of the Recalled Breathing machines and have knowingly misrepresented to Class Members the Recalled Breathing Machines possesses qualities and characteristics they do not have.

185. As a direct and proximate cause of Defendants unfair and unlawful methods of competition and unfair, deceptive, or unlawful acts or practices, Plaintiffs and Class Members have suffered actual damages. The Recalled Breathing Machines have failed due to their poor development, design, and unsuitability for their intended purpose, which will require (or has already required) Plaintiffs and Class Members to incur costs to prematurely repair and/or replace them, and be exposed to dangerous and unnecessary health hazards.

186. As a direct and proximate result of Defendants' unlawful, unfair, or fraudulent practices and the resulting exposure therefrom, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above. Defendants have been unjustly enriched and should be required to make restitution and/or disgorgement of funds paid to the Plaintiffs and Class Members to purchase new breathing devices or in the form of repair and/or replacement of the defective Recalled Breathing Machines pursuant to sections 17203 and 17204 of the California Business &

Professions Code.

EIGHTH CAUSE OF ACTION
Violation of Unfair Competition Law – Unfair Business Practice

187. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

188. Defendants engaged in an unfair business practice by knowingly failing to disclose material facts concerning the Recalled Breathing Machines.

189. Defendants' "unfair" practices were designed to induce Plaintiffs and Class Members, or their physicians, and/or third parties upon which Plaintiffs and Class Members relied to procure appropriate assisted breathing devices, to purchase the Recalled Breathing Machines and recommend the use of the Recalled Breathing Machines.

190. Defendants have failed to timely disclose the known and foreseeable harmful effects of polyester polyurethane when used in the Recalled Breathing Machines, all of which were known to Defendants before and after the machines were purchased, facts that would be and are material to the consumer or those third parties, on which consumers relied to procure appropriate assisted breathing devices.

191. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices and the resulting exposure therefrom, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above. Plaintiffs and Class Members have suffered actual damages. The Recalled Breathing Machines inflict substantial injury on Plaintiffs and the Class members due to inadequate product testing, poor design and/or development techniques, which will require Plaintiffs and Class Members to incur costs to prematurely repair and/or replace their assisted breathing devices.

192. Plaintiffs, on behalf of themselves and all others similarly situated, demand judgment against Defendants, for restitution and/or disgorgement of funds paid to Defendants by Plaintiffs and Class Members to purchase new breathing devices or in the form of repair and/or replacement of the defective Recalled Breathing Machines.

NINTH CAUSE OF ACTION
Unjust Enrichment

193. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 109 of this Complaint.

194. As the intended and expected result of its conscious wrongdoing, Defendants have profited and benefited from the purchase of the Recalled Breathing Machines by Plaintiffs and the Classes. Plaintiffs and Class Members' payments for the Recalled Breathing Machines flowed to Defendants.

195. Plaintiff Dr. Bastasch paid approximately $623.00 to purchase his REMStar 60 Series Auto with Bluetooth CPAP.

196. Plaintiff Dr. Mest purchased his Respironics Model DSX500HIIC CPAP device, at a cost to him of $1,596.00.

197. Defendants typically sell their Recalled Breathing Machines to consumers or end users indirectly.

198. Dr. Bastasch purchased his REMStar 60 Series Auto with Bluetooth CPAP from an online distributor, CPAP.com.

199. Dr. Mest purchased his Respironics Model DSX500HIIC CPAP device from Rotech Healthcare, Inc.

200. Defendants received some portion of Plaintiffs' money that was used to purchase their respective CPAP devices, as it passed through the two intermediary distributors. The exact amount of Plaintiffs' money that reached Defendants will be established, according to proof.

201. In this fashion, the benefit of Plaintiffs' money, namely the purchase price of the REMStar 60 Series Auto with Bluetooth CPAP and Respironics Model DSX500HIIC CPAP devices, was conferred on Defendants and retained by Defendants through the above-described distribution channels.

202. Most of the Recalled Breathing Machines were sold to consumers or end-users in some variation of the above system, with consumer or end-users paying distributors who buy the Recalled

Breathing Machines from the Defendants.

203. Thus, Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiffs and the Class, with full knowledge and awareness that, as a result of its misconduct, Plaintiffs and the Classes were not receiving products of the quality, nature, fitness or value that had been represented by Defendants, and that Plaintiffs and the Classes, as reasonable consumers, expected.

204. Defendants have been unjustly enriched by their fraudulent and deceptive withholding of benefits from Plaintiffs and the Classes, at the expense of Plaintiffs and the Classes.

205. Defendants have been further unjustly enriched in that the price paid by Plaintiffs and the Class Members for the Recalled Breathing Machines did not contemplate that consumers would bear the cost of replacing the defective Recalled Breathing Machines. At this time, Defendants have refused to replace the Recalled Breathing Machines or pay the cost of a new machine. All such expenses conferred an unjust benefit on Defendants by virtue of Defendants improperly shifting the burden of replacement costs to Plaintiffs and the members of the Class.

206. Defendants' retention of these profits and benefits is inequitable.

207. As a direct and proximate result of Defendants' unjust enrichment and the resulting exposure therefrom, Plaintiffs and the Class Members have incurred and will continue to incur injuries and losses as set out in Section E above. Plaintiffs and the Classes seek the disgorgement and restitution of Defendants wrongful profits, revenue, and benefits, plus interest, to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment against Defendants and in favor of Plaintiffs, and to award the following relief:

1. Certification of the Class with Plaintiffs appointed as class representatives and the undersigned appointed as Class Counsel;
2. Equitable and injunctive relief including but limited to:

a. Requiring Defendants to advise consumers affirmatively of their rights to all damages which they are lawfully afforded;

b. Requiring Defendants to fully disclose to all Class Members the risk of injury or harm resulting from the failure of the Recalled Breathing Machines;

c. A declaration that Defendants must disgorge, for the benefit of the Classes, all or part of its ill-gotten profits received from the sale of the defective the Recalled Breathing Machines, and/or to make full restitution to Plaintiffs and the Class Members;

3. An award of all actual, general, special, incidental, statutory, treble, or other multiple, punitive and consequential damages under statutory and common law as alleged in this Complaint, in an amount to be determined at trial, except that Plaintiffs do not seek damages under the CLRA yet;

4. An award to the Classes for economic injury due to the price premium that they paid at or following the point of sale;

5. An award of the costs of diagnostic testing for the early detection of illness, disease, and disease process and the purchase and replacement costs of the Recalled Breathing Machines in an amount to be determined at trial;

6. An award of pre-judgment and post-judgment interest at the maximum rate allowable by law;

7. An award of costs and attorneys' fees, as allowed by law, and/or from a common fund created hereby; and

8. Orders granting such other and further relief as may be appropriate.

JURY TRIAL DEMAND

Plaintiffs hereby demand a jury trial for all individual and Class claims so triable.

Dated: August 16, 2021

By: */s/ Michael F. Ram*
Michael F. Ram

MORGAN & MORGAN
COMPLEX LITIGATION GROUP
Michael F. Ram (SBN 104805)
mram@forthepeople.com
Marie N. Appel (SBN 187483)

mappel@forthepeople.com
711 Van Ness Avenue, Suite 500
San Francisco, CA 94102
Telephone: (415) 358-6913
Facsimile: (415) 358-6923

ROBINS KAPLAN LLP
Glenn A. Danas (SBN 270317)
GDanas@RobinsKaplan.com
2049 Century Park East, Suite 3400
Los Angeles, CA 90067
Telephone: (310) 229-5410

MORGAN & MORGAN COMPLEX LITIGATION GROUP
Kevin Hannon
(To be admitted Pro Hac Vice)
khannon@forthepeople.com
1641 Downing Street
Denver, CO 80218
Telephone: (303) 264-1769
Facsimile: (303) 264-1795

LAW OFFICE OF JUSTIN SOBODASH, PC
Justin Sobodash (SBN217450)
Justin@Sobodashlaw.com
8335 W. Sunset Blvd., Ste. 366
West Hollywood CA 90069
Telephone: (323) 337-9010
Facsimile: (323) 656-7155

AFFIDAVIT OF VENUE PURSUANT TO CIVIL CODE SECTION 1780(d)

I, Michael F. Ram, declare as follows:

1. I am an Attorney at Morgan & Morgan, Complex Litigation Group and one of the attorneys working on this case.

2. Pursuant to California Civil Code section 1780(d), this action has been filed in this county because Defendant is doing business in this county, and a substantial portion of the transaction, events or omissions giving rise to the claims occurred in this county.

I declare the foregoing to be true under penalty of perjury. Executed on August 13, 2021, at San Francisco, California.

/s/ Michael F. Ram
Michael F. Ram